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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,725	09/18/2003	Manabu Nakatani	01-1395	4358

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
08/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/664,725	NAKATANI ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on July 15, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application no. 11/560059 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 103(a) as being obvious over Gaviraghi (WO 00/27397 – see IDS) in view of Doi et al. (US PGPub No 2004/0058914) and as evidenced by Frisbee et al. (previously cited).

Gaviraghi teaches a tablet composition that includes telmisartan at 8 wt% (40 mg), sorbitol at 37 wt%, sodium hydroxide such that its molar ratio relative to telmisartan is 1:1, povidone as a binder at 10%, and monohydrate lactose as a binder (see example 2; instant claims 1-3 and 7-12). Gaviraghi teach that the excipients used in the composition are those conventionally known in the art (see page 7 line 28-page 8 line 5). As an oral dosage form whose components (sorbitol, monohydrate lactose, etc) are water soluble, the tablet matrix is interpreted as dissolving/disintegrating. This reference does not explicitly teach a polyoxamer in the composition.

Doi et al. teach that both polyvinylpyrrolidone (povidone) and Pluronic® F68, also known as poloxamer 188, were known as binders in solid pharmaceutical dosage forms at the time of the invention (see paragraph 448; instant claims 1 and 6).

Frisbee et al. teach that poloxamers (polyoxamers) are commonly known commercially available excipients (see abstract and page 5 lines 13-14 and 20-25). Frisbee et al. also teach that poloxamer 188 has an average molecular weight that is between 7680 and 9510 (see page 5 lines 27-28; instant claim 1).

As a known option that was used as a functional equivalent, it would have been obvious to one of ordinary skill in the art at the time of the invention to exchange the Pluronic® F68 taught by Doi et al. for the povidone of Gaviraghi. This obvious exchange would result in a poloxamer have a molecular weight between about 2000 and 12000

being present in the tablet of Gaviraghi, based upon the disclosure of Frisbee et al. Therefore claims 1-3 and 6-12 are obvious over Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al.

Claims 1-3, 6-9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGill et al. (Clinical Therapeutics 2001 23:833-849) in view of Raghunathan (US Patent No. 4,522,818) as well as Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. as applied to claims 1-3 and 6-12 above.

McGill et al. teach that the concurrent administration of hydrochlorothiazide (HCTZ), a diuretic, and telmisartan, an anti-hypertensive, resulted in the reduction of blood pressure in hypertensive patients (see page 836 column 2 paragraph 2 and page 846 column 1 paragraph 2). This modified reference does not explicitly teach that the HCTZ and telmisartan are in a bilayered tablet.

Raghunathan teaches a tablet with both a diuretic compound and anti-hypertensive compound (see abstract and column 1 lines 7-22).

Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. make obvious a tablet with telmisartan and excipients as detailed in instant claims 1-3 and 6-9. In addition, Gaviraghi teach a bilayered tablet configuration that includes telmisartan in one layer and another drug in the second layer (see page 13 1-2).

Based upon the teachings of McGill et al., telmisartan and HCTZ in a single tablet would have been desirable at the time of the invention, Raghunathan establishes that the concept of including a diuretic and anti-hypertensive in a single table was

already known at the time and Gaviraghi establishes that a bilayer organization for telmisartan and a second drug was also known. One of ordinary skill in the art would have found it obvious to organize a combination dosage form with HTCZ and telmisartan in a bilayer, based upon the teachings of Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. since the combination and configuration were known at the time of the invention and had a reasonable expectation of success. Therefore claims 1-3, 6-9, and 13 are obvious over McGill et al. in view of Raghunathan , Gaviraghi, and Doi et al. and as evidenced by Frisbee et al.

Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. as applied to claims 1-3 and 6-12 above, and further in view of Curatolo et al. (US Patent No. 6,068,859), Schneider (US Patent No. 6,358,986) and as evidenced by Gennaro (previously cited).

Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. make obvious the composition as claimed in instant claim 1. Although conventional methods of tablet preparation are taught generally, where granulation is explicitly envisioned, this modified reference does not explicitly teach the order of addition of all the composition components.

Curatolo et al. teach conventional methods of solid dosage form preparation as applicable to the production of their solid dosage forms (see column 12 lines 18-22). In particular, Curatolo et al. teach fluid bed granulation as one such known methodology where a binder and active are prepared in water as an aqueous solution that is then

applied to other solid particles (seed cores) in the composition (see column 12 lines 26-; instant claim 14).

Schneider teaches the solubilization of telmisartan in water by the addition of sodium hydroxide (see column 6 lines 17-20).

Gennaro teaches that fluidized bed granulation introduces a granulating solution onto suspended (fluidized) particles which then dry rapidly in the suspending air (see page 1625 column 2 paragraph 1 lines 1-4; instant claim 14).

Given that granulation was envisioned by Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. as a methodology to prepare their tablet composition and it was known to include binder along with a drug active in a granulation fluid for a fluidized bed, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine telmisartan with the poloxamer in the granulation fluid. Since it was also known that telmisartan was made water soluble by the inclusion of sodium hydroxide, it also would have been obvious to include sodium hydroxide in this fluid. The result would have been a method where the telmisartan, poloxamer and sodium hydroxide were prepared as a solution in water that was then combined with the other solid components (sorbitol – water soluble diluent) and granulated in a fluidized bed process that also dries the granulate. Therefore claims 1 and 14 are obvious over Gaviraghi in view of Doi et al., Schneider, and Curatolo et al. and as evidenced by Frisbee et al. and Gennaro.

Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. as applied to claims 1-3 and 6-12 above, and further in view of Schneider

Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. make obvious the composition as claimed in instant claim 1. Although conventional methods of tablet preparation are taught generally, where granulation is explicitly envisioned, this modified reference does not explicitly teach the order of addition of all the composition components.

Schneider teaches the solubilization of telmisartan in water by the addition of sodium hydroxide and the subsequent spray drying of the solution into particles that are mixed with the other components to be included in a tablet (see column 6 lines 17-20).

It would have been obvious to one of ordinary skill in the art to prepare a telmisartan granulate as taught by Gaviraghi in view of Doi et al. and as evidenced by Frisbee et al. (see Gaviraghi page 13 lines 12-13). This ordinarily skilled artisan would have found it obvious at the time of the invention to include the polyoxamer in the spray drying solution to aid its later combination with the other solid components as a known option for introducing this component into the composition that would have been within the technical grasp of one of ordinary skill. Therefore claims 1 and 15 are obvious over Gaviraghi in view of Doi et al. and Schneider and as evidenced by Frisbee et al.

Response to Arguments

Applicant's arguments filed July 16, 2009 have been fully considered but they are moot in light of the new grounds of rejection.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615